

REMARKSI. Status of the claims

Claims 1-6, 8, 9-31, and 35-39 are pending. Claims 7, 9, and 32-34 have been cancelled and claims 3, 13-19, 23-30, and 35-39 have been withdrawn to a non-elected aspect of the invention. In the outstanding official action, the examiner has raised patentability issues with regard to claims 1, 2, 4-6, 8, 9-12, 20-22, and 31. The applicants address the patentability of those claims in this response.

The applicants have amended claims 1, 5, 6, 8, 10, 12, 13, and 20. Support for the substantive amendments to claim 1 may be found on pages 11-12 of the specification and in original claims 7 and 9.

II. Abstract

In this paper, the applicants have provided the abstract of the disclosure requested by the examiner.

III. Objections to the claims

The examiner has objected to claims 7-10, 14-31, and 33-34 as being improperly based on a multiple dependent claim. The applicants have amended all non-withdrawn pending claims to place the claims in proper format.

The examiner has also objected to claims 12 and 13 as depending from themselves. The applicants have amended these claims to make the claims dependent on earlier-recited claims.

IV. Rejection under 35 U.S.C. § 101

The examiner has rejected claims 32-34 under 35 U.S.C. § 101 as claiming an improper definition of a process. The applicants have cancelled claims 32-34.

V. Enablement Rejection

The examiner has rejected claims 1-2, 4-12, 20-22, and 31-34 under 35 U.S.C. § 112, first paragraph as failing to be enabled by the specification. The examiner states that the specification is enabled for a method that employs mass spectrometry. In view of the limitation of claim 1 to mass spectrometry it is submitted that the characterization step in the method of claim 1 is enabled, in accordance with the examiner's suggestion.

The examiner states that the specification does not provide enablement for "any" compound according to the formula of claim 1. In view of the structural limitation to the compounds according to amended claim 1 it is submitted that the specification does enable any person skilled in the art to make and use any compound falling within the scope of amended claim 1 in the method for characterizing an analyte.

With respect to the breadth of claim 1, it is submitted that the compounds falling within the scope of amended claim 1 are now defined with sufficient particularity. The R' group of claim 1 has been limited to S, SO, NR¹, or O between the C atom that is in the β -position to the SO_n group and the reporter group or analyte. This limitation defines the cleavage point of the compound, which releases the reporter group for characterization by mass spectrometry. An example of the cleavage reaction of a compound according to claim 1 is disclosed in figure 9. It is also submitted that the nature of the analyte is not limited by this cleavage reaction and for the purposes of mass spectrometry the nature of the reporter group is not limited provided that its mass is known. See page 4, paragraph 2 and page 5, paragraph 3.

Regarding the quantity of experimentation needed to make or use the invention based on the content of the disclosure, it is submitted that a person skilled in the art would not require undue experimentation in order to be able to use the methods of the present invention. Specific examples of compounds falling within the scope of amended claim 1 may be found in the figures for the present application. As discussed above, the reporter group does not need to be particularly limited provided that it is readily detectable and can be related to an analyte in order to identify the analyte. In this regard, it is submitted that the skilled person would be able to identify a suitable reporter group which was readily detectable and which can be related to an analyte without undue experimentation.

In view of the foregoing, it is submitted that the rejection under 35 U.S.C. § 112, first paragraph (enablement) has been overcome. Therefore, the applicants request the withdrawal of this rejection.

VI. Written description rejection

The examiner has rejected claims 1-2, 4-12, 20-22, and 31-34 under 35 U.S.C. § 112, first paragraph as failing to provide written description support from the specification.

In view of the structure limitation to the compounds according to claim 1, it is submitted that the person skilled in the art would be able to clearly identify compounds that

fall within the scope of the invention. The structural limitation defines the way in which the analyte and reporter group are linked and also defines the cleavage point of the compound. Further, this limitation defines the common structural attributes of all the compounds falling within the scope of claim 1. The specification discloses a number of examples of compounds falling within the scope of amended claim 1. However, as discussed above, the skilled person does not require any structural features of the analyte or the reporter group in order to determine which compounds fall within the scope of amended claim 1. As such, it is submitted that the applicant is entitled to claim the scope of compounds provided in the method of amended claim 1 and the examiner's objection with respect to written description is now overcome.

Furthermore, claim 1, both before and after the amendments made in this response, clearly has written support from both the specification and the originally filed claims. Yet the examiner's concerns, as detailed in this rejection, seem not to lie in whether the claims have written description support, but rather in the alleged lack of guidance from the specification. While it is proper for the examiner to raise such concerns, if present in the claims, the applicants respectfully request that the examiner address these issues in an enablement rejection, not a written description rejection.

VII. Rejections under 35 U.S.C. § 112, second paragraph

The examiner has rejected claims 1-2, 4-12, 20-22, and 31-34 under 35 U.S.C. § 112, second paragraph as failing to particularly point out and distinctly claim the subject matter.

In paragraph A, the examiner objects to the R, R', X, and X' groups recited in claims 1-2, 4-12, 20-22, and 31-34 as defined only by functional properties. According to the examiner, a claim to a material defined solely in terms of what it can do, or a property thereof, does not particularly point out the claimed invention. However, as set forth in MPEP § 2173.05(g), there is nothing inherently wrong with defining some part of an invention in a functional terms. Functional language does not, in and of itself, render a claim improper. See *In re Swinehart*, 439 F.2d 210 (CCPA 1971). Accordingly, the rejected claims are not indefinite or unclear by their use of functional language. If the examiner's concern lies in the breadth of the claim, the applicants again respectfully request that the examiner address the enablement issues in an enablement rejection, not an indefiniteness rejection.

In paragraph B, the examiner objects to the terms "D" and "F" recited in claim 6. The applicants have amended claim 6 to clarify that the letters refer to "deutrium" and "fluorine," respectively.

In paragraph C, the examiner objects to the term "NR¹" recited in claim 7 because the R¹ is not defined. The applicants have incorporated claim 7 into claim 1 and identified the R¹ substituent.

In paragraph D, the examiner has objected to claims 6, 12, 16, 19, and 23 as being in improper Markush format. The applicants have amended claims 6 and 12 to put the claims in proper format. Claims 16, 19, and 23 are withdrawn and need not be amended at this stage.

In paragraph E, the examiner has objected to claim 12 and 13 as failing to depend upon another claim. As set forth in section III of this paper, these claims have been amended to place them in proper format.

In paragraph F, the examiner has objected to claim 17 as alleging that in instances when m is 1, S cannot be sulfur. When m is 1, the sulfur of the cysteine has been oxidized by a reagent, such as hydrogen peroxide. This process is described on page 13 of the description. As such, when m is 1 the S can be the sulfur atom in the cysteine.

In paragraphs G and H, the examiner has raised objections with regard to claims 32-34. The applicants have cancelled these claims.

In view of the foregoing comments and amendment to the claims, the applicants request the withdrawal of the rejections based upon 35 U.S.C. §112, second paragraph.

VIII. Rejection under 35 U.S.C. § 102(b)

The examiner has rejected claims 1, 2, 4-9, 11-12, 20, and 31-34 under 35 U.S.C. § 102(b) as being anticipated by the article authored by Nothnagel ("Nothnagel"). The applicants respectfully traverse this rejection.

Nothnagel discloses the synthesis of fluorescent lipid probes composed of Lucifer yellow dyes linked to either cholesterol or phospholipids for use in labeling and studying cell membranes. Figure 1B shows the chemical structure of a phospholipid probe. These probes were analyzed using fast atom bombardment mass spectrometry. See figure 2. The probes insert into plasma membranes of cells where they remain localized, which allows the labeling and study of cell membranes.

Nothnagel does not disclose a method for characterizing an analyte according to claim 1 of the present invention. As discussed above, Nothnagel discloses a method for

Nothnagel does not disclose a method for characterizing an analyte according to claim 1 of the present invention. As discussed above, Nothnagel discloses a method for producing a probe for labeling cell plasma membranes which does not involve characterization of an analyte.

It is the examiner's opinion that Nothnagel anticipates claim 1 firstly because figure 1B falls within the scope of the formula of claim 1. Compound 1B in Nothnagel does fall within the scope of the general formula of claim 1. However, in the context of the method of claim 1, figure 1B does not disclose a compound with a reporter group and an analyte as recited in claim 1. The compound of figure 1B represents the whole probe which is used to label cell membranes. The applicants do not agree with the examiner's opinion that the Lucifer Yellow Dye (LY) part represents the reporter group and the DC_{12:0}PE part represents the analyte.

Secondly, the examiner also considers that Nothnagel discloses cleaving the reporter group from the analyte due to the cleavage of DC_{12:0}PE from LY by FAB mass spectrometry. Figure 2 may disclose the uncontrolled cleavage of DC_{12:0}PE from LY by FAB mass spectrometry used to analyze the whole probe. However, this is not the same as the specific step of cleaving the reporter group from the analyte according to the present invention wherein the compound, at a particular point, is cleanly cleaved into two parts. In contrast, the probe in Nothnagel is cleaved into many different parts and does not split the compound in the correct place.

Thirdly, the examiner considers that Nothnagel discloses identifying the reporter group, thereby characterizing the analyte in figure 2. However, Nothnagel does not disclose the characterization of an analyte by identification of a reporter group. The FAB mass spectrometry used in Nothnagel was used to characterize and identify the whole probe not to identify the FY part of the probe to characterize the DC_{12:0}PE part of the probe. Further, Figure 2 in Nothnagel does not show a mass ion peak for LY, which would suggest that LY is not used as a reporter group, as recited in the present invention. Still further, Nothnagel does not disclose that the mass-to-charge ratio of the reporter group is determined to identify the analyte, as recited in amended claim 1 of the present invention.

The examiner also considers that the compounds disclosed in claims 2, 4-9 and 11-12 are anticipated by the disclosure of Nothnagel in figures 1B and 2. However, it is submitted that, as discussed above, Nothnagel does not anticipate the method claimed in the present

Application No.: 09/743,746
Attorney Docket No.: 068800-0276611

invention. Therefore, the applicants request the withdrawal of the rejection based upon 35 U.S.C. §102(b).

Application No.: 09/743,746
Attorney Docket No.: 068800-0276611

IX. Conclusion

The applicants believe that this amendment and response addresses all issues raised by the examiner in the outstanding official action. If any issues in the prosecution of this application remain unresolved, the Examiner is encouraged to contact the undersigned counsel at the number listed below in order to resolve such issues.

Please charge any fees associated with the submission of this paper to the applicants' Deposit Account No. 033975. The Director is also authorized to credit any overpayments to the above-referenced Deposit Account.

Respectfully submitted,

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